K091263 p1/2

510(k) Summary

NOV 19 2009

Submitter information

Company name	Materialise N.V.
Establishment registration number	3003998208
Street Address	Technologielaan 15
City	Leuven
Postal code	3001
Country	Belgium
Phone number	+32 16 39 66 75
Fax number	+32 16 39 66 06
Contact name	Karl vom Berge
Contact title	Product Manager
Contact e-mail address	karl.vomberge@materialise.be

Submission date

The date of the Traditional 510(k) submission is April 29th, 2009. The date of the Additional Information request submission is August 4th 2009.

Submission information

Trade Name	Zimmer Patient Specific Instruments Zimmer Patient Specific Instruments Planner
Common Name	Knee prosthesis
Classification Name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis Knee joint patellofemorotibial. metal/polymer porous-coated uncemented prosthesis
Product code	JWH (21 CFR § 888.3560) and MBH (21 CFR § 888.3565)

Predicate device

Predicate Device	
Trade or proprietary or model name	**Patient Matched Cutting Blocks**
510(k) number	**K082358**
Decision date	**11/25/2008**
Product code	**JWH, MBH**
Manufacturer	**Smith and Nephew, Inc.**

Device Information

Description of the device

The **Zimmer Patient Specific Instruments System** consists of a software component, **Zimmer Patient Specific Instruments Planner** and a hardware component, **Zimmer Patient Specific Instruments** and is designed to assist the surgeon in the placement of total knee

replacement components for Zimmer NEXGEN CR-FLEX fixed bearing and Zimmer NEXGEN LPS-FLEX fixed bearing prostheses families.

Functioning of the device

The Zimmer Patient Specific Instruments System generates a pre-surgical plan based on MRI imaging data using the Zimmer Patient Specific Instruments Planner (software component). The software is then used pre-operatively by a qualified surgeon to inspect, fine-tune and approve the pre-surgical plan. Next, Zimmer Patient Specific Instruments are designed and manufactured based on the approved pre-surgical plan. Zimmer Patient Specific Instruments are patient specific templates that transfer the pre-operatively determined positioning of the Total Knee Replacement components to the patient intra-operatively, assisting the surgeon in positioning and aligning the actual Total Knee Replacement components by guiding and marking drill locations.

Intended use

The **Zimmer Patient Specific Instruments System** is intended to be used as a surgical instrument to assist in the positioning of Total Knee Replacement components intra-operatively and in guiding the marking of bone before cutting. The Zimmer Patient Specific Instruments System is to be used with Zimmer NEXGEN CR-FLEX fixed bearing and Zimmer NEXGEN LPS-FLEX fixed bearing prostheses families only.

The Zimmer Patient Specific Instruments are intended for single use only.

Summary of technological characteristics

Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the predicate device.

Performance data

Non-clinical tests

Non-clinical tests were performed to assess the safety and effectiveness of the device. Testing verified that the accuracy and performance of the system is adequate to perform as intended.

Clinical data

Not applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 15 2011

Materialise N.V.
% Mr. Karl vom Berge
Technologielaan 15
3001 Leuven
Belgium

Re: K091263
Trade/Device Name: Zimmer Patient Specific Instruments System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: OOG, JWH
Dated: October 22, 2009
Received: October 26, 2009

Dear Mr. vom Berge:

This letter corrects our substantially equivalent letter of November 19, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

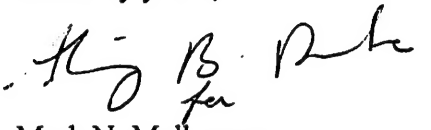
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091263

Device Name: Zimmer Patient Specific Instruments System (Zimmer Patient Specific Instruments, Zimmer Patient Specific Instruments Planner)

Indications For Use:

The Zimmer Patient Specific Instruments System is intended to be used as a surgical instrument to assist in the positioning of Total Knee Replacement components intra-operatively and in guiding the marking of bone before cutting. The Zimmer Patient Specific Instruments System is to be used with Zimmer NEXGEN CR-FLEX fixed bearing and Zimmer NEXGEN LPS-FLEX fixed bearing prostheses families only.

The Zimmer Patient Specific Instruments are intended for single use only.

Prescription Use _ X _____ AND/OR Over-The-Counter Use __ _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091263